Massachusetts Department of Public Health
Board of Registration in Pharmacy
Drug Control Program

JOINT POLICY 2012- 01:
PERMITTED PRESCRIPTION CHANGES AND ADDITIONS AFTER CONSULTATION WITH PRESCRIBER

Introduction

The Massachusetts Department of Public Health, through the Board of Registration in Pharmacy (Board) and the Drug Control Program (DCP), adopts Joint Policy 2012- 01, which advises pharmacists of the changes or additions that may be made to a controlled substances prescription after consultation with the prescribing practitioner (prescriber) or authorized agent of the prescriber (agent).

According to guidance (August 24, 2011 DEA letter) issued by the U.S. Drug Enforcement Administration (DEA), "whether it is appropriate for a pharmacist to make changes to a prescription . . . varies case-by-case based on the facts present. Consequently, DEA expects that when information is missing from or needs to be changed on a schedule II prescription, pharmacists use their professional judgment and knowledge of state and federal laws and policies to decide whether it is appropriate to make changes to that prescription." (see links below)

Joint Policy 2012- 01 provides the state requirements for changes and additions for Schedule II and, separately, Schedules III-V prescriptions.

Regulatory Background

In 2007, DEA published a Final Rule (Rule) titled Issuance of Multiple Prescriptions for Schedule II Controlled Substances. (72 FR 64921). In the Rule's preamble, DEA stated that: *"the essential elements of the [Schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed) ... may not be modified orally."* DEA has since stated in a 2008 letter (see links below) its intentions to amend the Rule, acknowledging that the instructions in the Rule preamble, as quoted, conflict with a previous DEA policy permitting the same changes to a Schedule II prescription that a pharmacist may make to a Schedule III, IV or V prescription after consultation with the prescriber or agent. As noted above, DEA has advised pharmacists to make changes to a Schedule II prescription in accordance with the laws, regulations and policies of their particular state. DEA has also provided guidance on permitted pharmacist changes to Schedules III-V prescriptions

(October 15, 2008 DEA Policy Letter)

(August 24, 2011 DEA Policy Letter to NABP article posted September 1, 2011)

http://www.deadiversion.usdoj.gov/faq/general.htm#rx-8

http://www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr1006.htm

JOINT POLICY 2012- 01:
PERMITTED PRESCRIPTION CHANGES AND ADDITIONS AFTER CONSULTATION WITH PRESCRIBER OR PRESCRIBER AGENT

Until a new DEA rule or policy is in effect, the Board and DCP issue this Joint Policy advising Massachusetts pharmacists that, in exercising their professional judgment and corresponding responsibility to ensure that prescriptions conform in all essential respects to laws and regulations, they may make changes and additions to a controlled substances prescription as delineated below. Note: The pharmacist is NEVER permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law) or the prescriber's signature.

Prescription information that a pharmacist may NEVER change or add

For ALL schedules (Schedule II – VI) the following prescription information may NEVER be changed or added (a new prescription would be required)

Patient's name
Drug (controlled substance) product (except for permitted generic substitution)
Prescriber's name
Prescriber's signature
Issue date/Earliest date to be filled*

* Earliest date to be filled
- In the Rule response to public comments, DEA affirmed that no oral modifications may be made to the earliest date that a Schedule II prescription may be filled.

- Regarding the Rule, Federal Regulation 21 CFR 1306.14(e) states: "Where a prescription that has been prepared in accordance with section 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the Schedule II prescription before that date." http://www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_14.htm

Prescription information that a pharmacist MAY change or add

1. **SCHEDULE II Prescriptions**

Schedule II prescription information that a pharmacist MAY change or add after consultation with prescriber

Date written
Patient's address*
Directions for use
Refill Information
Generic substitution (as permitted by state law)
Prescriber's address
Prescriber's DEA No. **
Dosage form
Drug strength
Quantity prescribed

* A patient's address may be:
(a) added if not included on the original prescription, without consultation with the prescriber or agent; or
(b) changed after consultation with the prescriber or agent.

** A Prescriber's DEA No. may be added to a valid prescription without consultation with the prescriber or agent.

Methods for prescriber to communicate Schedule II prescription information changes or additions

(a) **Written**
A prescriber may provide written changes or additions by mail or electronic transmission, including e-mail and facsimile. The pharmacist must attach the written changes, including notation of receiving the changes, on the original prescription. In addition, the pharmacist must document the date and name of the prescriber authorizing the changes to the prescription.

(b) **Oral**
A prescriber may orally communicate changes or additions to the pharmacist. The pharmacist must document the date, changes or additions and the name of the authorizing prescriber on the front or back of the original prescription.

2. SCHEDULE III - VI Prescriptions

Schedule III – VI prescription information that a pharmacist may change or add after consultation with prescriber or agent

Date written
Patient's address*
Directions for use
Refill information
Generic substitution (as permitted by state law)
Prescriber's address
Prescriber's DEA No. **
Dosage form
Drug strength
Quantity prescribed

* A patient's address may be:
(a) added if not included on the original prescription, without consultation with the prescriber or agent; or
(b) changed after consultation with the prescriber or agent.

** A Prescriber's DEA No. may be added to a valid prescription without consultation with the prescriber or agent.

Methods for prescriber or agent to communicate Schedule III-VI prescription information changes or additions

(a) **Written**
A prescriber or agent may provide written changes or additions by mail or electronic transmission, including e-mail and facsimile. The date, changes or additions, and the name of the authorizing prescriber or agent must be documented on the front or back of the original prescription.

(b) **Oral**

A prescriber or agent may orally communicate changes or additions. The date, changes or additions, and the name of the authorizing prescriber or agent must be documented on the front or back of the original prescription.

JOINT POLICY 2012-01

Authority: G.L. c. 112, § 42A; G.L. c. 94C, §§ 18 through 22; 247 CMR 2.00 et seq.
Adopted by the Board of Registration in Pharmacy: January 10, 2012